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APPLICATION NO.	FIL	ING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,708	08/31/2001		Richard B. Thompson	3645-0104P	9931
2292	7590	05/07/2004		EXAMINER	
BIRCH ST PO BOX 74		COLASCH & BIR	SRIVASTAVA, KAILASH C		
FALLS CHURCH, VA 22040-0747				ART UNIT	PAPER NUMBER
				1651	
				DATE MAILED: 05/07/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Summary	09/942,708	THOMPSON ET AL.				
	Examiner	Art Unit				
The MAILING DATE of this communication and	Dr. Kailash C. Srivastava	1651				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 05 Ma	arch 2004.					
	action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>2,5,8,13,23 and 25-33</u> is/are pending in the application.						
4a) Of the above claim(s) <u>8,23 and 25-33</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>2,5 and 13</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accept		xaminer.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4)  Interview Summary (F Paper No(s)/Mail Date	PTO-413)				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date		ent Application (PTO-152)				

#### **DETAILED ACTION**

1. Applicants' response and amendment filed March 05, 2004 in response to Office Action mailed November 05, 2003 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

#### Claims Status

2. Claims 2, 5, 8, 13, 23 and 25-33 are pending.

#### Restriction/Election

3. Applicants argue that the Examiner has rejoined Claim 8, but said Claim has not been Examined in the Office Action mailed November 05, 2003. Applicants also argue that Claim 23 and newly presented Claims 25-33 should be examined together with applicants' currently elected invention encompassing Claims 2, 5 and 13.

With regard to applicants' argument on non-examination of Claim 8 in Office Action mailed November 05, 2003, Applicants should note that the Examiner has clearly stated on Page 3, item 4 of the Office Action mailed November 5, 2003, that "Claims 2, 5 and 13 are examined on merits in so far as they read on the elected species". To further clarify applicants' confusion in this regard, Claim 8 was removed from Group III (Applicants' elected group for prosecution according to Page 9, Lines 7-10 of Applicants' election filed August 22, 2003) and rejoined to invention Claimed in Group I because Claim 8 is drawn to a composition comprising an apocarbonic anhydrase protein conjugated to photo luminescent compounds which is the subject matter of invention drawn to claims encompassed in Group I (See, Page 2, item 2 of the Office Action mailed on November 05, 2003).

Applicants' arguments regarding examination of Claim 23 in current application have been fully considered but are not found persuasive for the reasons of record on Page 2, Lines 24 to 26 of the Office Action mailed on November 05, 2003. Furthermore, the invention currently under prosecution in Applicants' currently elected Group III encompassing Claims 2, 5 and 13 is drawn to a composition comprising a mixture of an apo-carbonic anhydrase and photoluminescent compounds. Said composition is completely different than the components comprising the kit of Claim 23 and newly presented Claims 25-33 dependent on Claim 23.

Applicants have already elected Claims 2, 5 and 13 instantly under prosecution (See Page 9, Lines 7-10 of Applicants' election filed August 22, 2003). Accordingly, Examiner reiterates that Claims 8 and 23 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Since newly presented Claims 25-33 depend from Claim 23, those claims are also withdrawn for the same reason as Claim 23.

This application contains claims 8, 23 and 25-33 drawn to an invention nonelected with traverse in the Paper filed August 18, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. Amended Claims 2 and 13 and originally presented Claim 5 are examined on merits.

# Claim Rejections - 35 U.S.C. § 103

5. Claims 2, 5 and 13 stand rejected under 35 U.S.C. § 103 (a) as obvious over Thompson et al. (U.S. Patent 5,545,517) and Thompson et al. (Journal of Fluorescence, 1992, 5, Pages 123-

130) in view of Toyo'oka et al. (New Fluorogenic Reagent having halogenbenzofurazan structure for Thiols. 1984. Anal. Chem., 56, Pages 2461-2464).

6. Applicants argue that the "Examiner has not properly established *prima facie* obviousness of the claimed invention and Examiner's rejection is seen as a hindsight reconstruction of the instantly claimed invention".

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicants' arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5

USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

Toyo'oka et al. teach that reacting ABD-F with mercaptoethanol yields the fluorphore, 4-(2-Hydroxyethylthio)-7-aminosulfonyl-2, 1, 3-benzoxadiazole, (Table III) with a relative fluorescence in excess of the parent compound ABD-F (RFI = 122). Additional advantages of applying this fluorogenic reagent (i.e., 4-(2-Hydroxyethylthio)-7-aminosulfonyl-2, 1, 3-benzoxadiazole) over dansyl-compounds (e.g., dansylaziridine) are: 4-(2-Hydroxyethylthio)-7-aminosulfonyl-2, 1, 3-benzoxadiazole facilitates clear detection, does not give an interfering background fluorescence, has a long fluorescence wave-length so that interfering endogenous fluorescent materials in biological samples can be avoided but rather it fluoresces specifically only when combined with an analyte, i.e., (human) apo-carbonic anhydrase (Column 1, Lines 26-32 and 39-52). Hence, ABD-F is clearly advantageous over dansyl and would be reasonably suggested to substitute for dansyl in the composition of Thompson et al.

Applicant's arguments filed March 05, 2004 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103 is adhered to for the reasons of record and the additional reasons above.

### **CONCLUSION**

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

- 8. No Claims are allowed.
- 9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571) 272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.

Patent Examiner

Art Unit <u>1651</u>

(571) 272-0923

May 6, 2004

Jon P. Weber, Ph.D. Primary Examiner